REMARKS

Claims 1-3, 5-7, 20, 21, and 34-36 are pending in the application.

The office action rejects claims 1-3, 5-6, 14-15, 19-21, and 34-36 under 35 USC §103(a) as being unpatentable over EP 506,207 in view of applicant's disclosure. Claims 16-18 stand rejected on that basis in addition to the Merck Index to show that lecithin as a surfactant and emulsifier to increase the adsorption of the topical composition.

The Examiner agrees that EP 506,207 does not expressly teach the use of 8-hydroxyquinoline; but points to Applicant's own disclosure to show that this substance may be used as an antimicotic. Therefore, the Examiner argues that the claimed composition would be obvious on the basis that 8-hyrdoxyquinoline could be used as an alternative to the nonexclusive list of other analogous antimicotics that are listed in EP 506,207. In other words, the Examiner finds that the claimed composition is an obvious antimicotic due to the known functional similarity of the related analogs including sulfated and halogenated forms of 8-hydroxyquinoline. Furthermore, the Examiner finds that the recitation of efficacy against various cancerous lesions is not structure, and so carries no patentable weight.

In response, Applicant first observes that the claimed recitation of efficacy against various lesions does in this instance carry patentable weight because: (a) this functionality inherently flows from what is claimed and (b) this language clarifies that the claimed composition has this functionality.

Applicant next observes that the remarks on page 3 of the Office Action dated December 26, 2007 are in error to the extent that they characterize as irrelevant Applicant's arguments to the effect that the rejection has been fully rebutted by a showing of nonequivalence. Our response dated October 26, 2004, a Declaration of Carl Hansen showing that the use of 8-hydroxyquinoline in the claimed composition was effective against precancerous lesions, whereas the sulfated form had a total lack of efficacy. This is significant evidence forming a complete rebuttal to the case for obviousness that the Examiner has asserted.

Assuming for the purpose of argument that the Examiner has made a prima facie showing of obviousness on the basis that the claimed composition would be useful as an antimicotic composition, this does not necessarily show obviousness if the claimed

composition possesses unexpected properties that are not found in the compositions expressly taught in the prior art. A *prima facie* case for obviousness, even if one presently exists, may be rebutted on this basis.

> This court, in reconsidering this case in banc, reaffirms that structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a *prima facie* case of obviousness, and that the burden (and opportunity) then falls on an applicant to rebut that *prima facie* case. Such rebuttal or argument can consist of a comparison of test data showing that the claimed compositions possess unexpectedly improved properties or properties that the prior art does not have (*In re Albrecht*, 514 F.2d 1389, 1396, 185 USPQ 585, 590 (CCPA 1975); *Murch*, 464 F.2d at 1056, 175 USPQ at 92), that the prior art is so deficient that there is no motivation to make what might otherwise appear to be obvious changes (*Albrecht*, 514 F.2d at 1396, 185 USPQ at 590; *In re Stemniski*, 58 C.C.P.A. 1410, 444 F.2d 581, 170 USPQ 343 (CCPA 1971); *In re Ruschig*, 52 C.C.P.A. 1238, 343 F.2d 965, 145 USPQ 274 (CCPA 1965)), or any other argument or presentation of evidence that is pertinent.

In re Dillon, 919 F.2d 688, 693 (Fed. Cir. 1990)

Here the Examiner argues that the functionality of the clamed composition is a newly discovered property that was always inherent to the prior art compositions; however, that position is factually rebutted by the showing of nonequivalence in the declaration of Carl Hansen. Representative comparative concentrations of materials show that the claimed composition is effective against eosinophillic infection. The patent specification itself documents efficacy against various types of cancers and precancerous lesions. In contrast, the same composition where the sulfated form of 8-hydroxyquinoline is used is not effective. With the halogenated forms of 8-hydroxyquinoline now understood to be themselves carcinogenic, this evidence comprises a legally competent rebuttal under the *Dillon* standard, since it is "a comparison of test data showing that the claimed compositions possess unexpectedly improved properties or properties that the prior art does not have." The prior art makes no teaching or suggestion to make the change of using 8-hydroxyquinoline for the

purpose of gaining these heretofore unrecognized advantages. Furthermore, even if some members of the group of antimicotics yield this functionality and others do not (a showing that is as yet unsupported by any evidence at all) it would remain a patentable advance to recognize which ones do and which ones do not have the functionality. Accordingly, for these multiple reasons , it is entirely on point that the Declaration of Carl Hansen points to nonequivalence among the broad group. It is patentable that we are claiming the use of a particular antimycotic –8-hydroxyquinoline—that was (a) not disclosed in EP 506,207, and (b) is shown to have the functional advantage of an effect that differs in kind that is now also claimed. *See also In re Papesch*, 315 F.2d 381, 388 (CCPA 1963) ("To those skilled in the chemical art, one homologue is not such an 'advance' over an adjacent member of the series as requires invention, unless the beneficial properties realized in the new homologue lie clearly outside of the expectations which knowledge of his science would inform the trained chemist should be inherent in the product.")

The claims are patentable for the above reasons. This response is being filed with required fees for a Request for Continued Examination and Petition for Extension of Time. Applicant believes that no additional fees are due at this time. However, if any additional fees are due, the Commissioner is authorized to charge them to deposit account No. 12-0600.

Respectfully submitted,

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